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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Stan Gronthos et al.

Serial No. : 10/551,162 Group Art Unit: 1644

Filed : March 29, 2004 Examiner: Michail A. Belyavskiy

Title : PERIVASCULAR MESENCHYMAL PRECURSOR CELLS

1185 Avenue of the Americas
New York, New York 10036
May 27, 2008

MAIL STOP AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In accordance with the duty of disclosure under 37 C.F.R. §1.56, applicants direct the Examiner's attention to the following items, which are listed on the Substitute Form PTO-1449 attached hereto as (**Exhibit A**). Items 1-29 are U.S. Patents or U.S. Patent Application Publications. No copies of these items are attached hereto as permitted by 37 C.F.R. §1.98(a)(2)(ii). Copies of items 30-122 are attached hereto as **Exhibits 1-93**, respectively:

1. U.S. Patent No. 5,197,985 issued to Caplan et al. on March 30, 1993;
2. U.S. Patent No. 5,226,914 issued to Caplan et al. on July 13, 1993;

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3. U.S. Patent No. 5,486,359 issued to Caplan et al. on January 23, 1996;
4. U.S. Patent No. 5,591,625 issued to Gerson et al. on January 7, 1997;
5. U.S. Patent No. 5,811,094 issued to Caplan on September 22, 1998;
6. U.S. Patent No. 5,827,740 issued to Pittenger on October 27, 1998;
7. U.S. Patent No. 5,837,539 issued to Caplan et al. on November 17, 1998;
8. U.S. Patent No. 5,922,597 issued to Verfaillie et al. on July 13, 1999;
9. U.S. Patent No. 5,980,887 issued to Isner et al. on November 9, 1999;
10. U.S. Patent No. 6,022,540 issued to Bruder et al. on February 8, 2000;
11. U.S. Patent No. 6,087,113 issued to Caplan et al. on July 11, 2000;
12. U.S. Patent No. 6,261,549 issued to Fernandez et al. on July 17, 2001;
13. U.S. Patent No. 6,322,784 issued to Pittenger et al. on November 27, 2001;
14. U.S. Patent No. 6,335,195 issued to Rodgers et al. on January 1, 2002;
15. U.S. Patent No. 6,387,367 issued to Davis-Sproul et al. on May 14, 2002;
16. U.S. Patent No. 6,387,369 issued to Pittenger et al. on May 14, 2002;
17. U.S. Patent No. 6,645,727 issued to Thomas et al. on November 11, 2003;

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18. U.S. Patent No. 6,709,864 issued to Pittenger et al. on March 23, 2004;
19. U.S. Patent No. 6,875,430 issued to McIntosh et al. on April 5, 2005;
20. U.S. Patent No. 7,122,178 issued to Simmons et al., on October 17, 2006;
21. U.S. Patent No. 5,405,772 issued to Ponting et al., April 11, 1995;
22. U.S. Patent Application Publication No. 2004-0107453, published June 3, 2004;
23. U.S. Patent Application Publication No. 2006-0008452 published January 12, 2006;
24. U.S. Patent Application Publication No. 2005-0019911 published January 27, 2005;
25. U.S. Patent Application Publication No. 2005-0158289 published July 21, 2005;
26. U.S. Patent Application Publication No. 2005-0281790 published December 22, 2005;
27. U.S. Patent Application Publication No. 2002-0085996, published July 2002;
28. U.S. Patent Application Publication No. 2006-0286077 A1 published December 21, 2006;
29. U.S. Patent Application Publication No. 2006-0193840 A1 published August 31, 2006;
30. PCT International Publication No. WO 01/011011, published February 15, 2001; (**Exhibit 1**)
31. PCT International Publication No. WO 04/84921 A1, published October 7, 2004; (**Exhibit 2**)
32. PCT International Application Publication No. WO 04/85630 A1 published October 7, 2004; (**Exhibit 3**)

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33. PCT International Publication No. WO 99/003973 A, published January 28, 1999; **(Exhibit 4)**
34. Hellström M, Kalén M, Lindahl P, Abramsson A, and Betsholtz C. (1999) Role of PDGF-B and PDGFR- β in recruitment of vascular smooth muscle cells and pericytes during embryonic blood vessel formation in the mouse. Development 126: 3047-3055; **(Exhibit 5)**
35. International Search Report issued by the International Searching Authority (ISA/AU) on May 17, 2004 in connection with International Application No. PCT/AU2004/000417; **(Exhibit 6)**
36. International Preliminary Report on Patentability issued by the International Bureau of WIPO on October 1, 2005 in connection with International Application No. PCT/AU2004/000417; **(Exhibit 7)**
37. Alberico et al. (1987) Blood 69, page 1120-1127; **(Exhibit 8)**
38. Allen, T.D., (1981) "Haemopoietic Microenvironments in vitro: ultrastructural aspects" CIBA Found. Symposium 84, pages 38-67; **(Exhibit 9)**
39. Allen et al. (1990) "Marrow Biology and Stem Cells" Immunol. Ser. 49, pages 1-38; **(Exhibit 10)**
40. Anklesaria et al. (1989) Blood 74, page 1144-1151; **(Exhibit 11)**
41. Anklesaria et al. (1987) Proc. Nat'l Acad. Sci. USA 84, page 7681-7685; **(Exhibit 12)**
42. Bennett, J.H. et al. (1991) J. Cell Sci. 99(1), page 131-139; **(Exhibit 13)**
43. Bentley, S.A. (1982) Br. J. Haematol 50(1), pages 1-6; **(Exhibit 14)**

44. Castro-Malaspina et al. (1980) "Characterization of Human Bone Marrow Fibroblast Colony-Forming Cells and Their Progeny" Blood 56, pages 289-301; (**Exhibit 15**)
45. Castro-Malaspina et al. (1981) "Human Megakaryocyte Stimulation of Proliferation of Bone Marrow Fibroblasts" Blood 57, pages 781-787; (**Exhibit 16**)
46. Clarke, Emer, "Mesenchymal Cells" www.stemcell.com (mini-review); (**Exhibit 17**)
47. Dexter et al. (1977) "Conditions Controlling the Proliferation of Haemopoietic Stem Cells in Vitro" J. Cell Physiol. 91, pages 335-344; (**Exhibit 18**)
48. Dexter et al. (1984) Kroc Found. Ser. 18, pages 57-96; (**Exhibit 19**)
49. Doherty, M.J. et al. (1998) "Vascular Pericytes Express Osteogenic Potential In Vitro and In Vitro" J. Bone and Mineral Research 13, pages 828-838; (**Exhibit 20**)
50. Fong et al. (1997) "Nonradioactive, Agarose Minigel Procedure for Telomeric Repeat Amplification Protocol" BioTechniques 23, pages 1029-1032; (**Exhibit 21**)
51. Friedenstein (1976) Int'l R. Cytology 47, pages 327-359; (**Exhibit 22**)
52. Friedenstein (1980) "Stromal Mechanisms of Bone Marrow: Cloning in Vitro and Retransplantation in Vivo" Immunology of Bone Marrow Transplantation, pages 19-29 Haematol. Blood Transfusion; (**Exhibit 23**)
53. Friedenstein et al. (1970) "The Development of Fibroblast Colonies in Monolayer Cultures of Guinea-Pig Bone Marrow and Spleen Cells" Cell Tissue Kinetics 3, pages 393-403; (**Exhibit 24**)

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54. Friedenstein et al. (1992) Bone and Mineral 18, pages 199-213; (**Exhibit 25**)
55. Gronthos, S., et al. (1994) "The STRO-1+ Fraction of Adult Human Bone Marrow Contains the Osteogenic Precursors," Blood 84, pages 4164-4173; (**Exhibit 26**)
56. Gronthos, S., et al. (1995) Blood 85, pages 929-940; (**Exhibit 27**)
57. Huang and Terstappen (1992) Nature 360, pages 745-749; (**Exhibit 28**)
58. Keating et al. (1982) Nature 298, pages 280-283; (**Exhibit 29**)
59. Kim et al. (1994) Science 266, pages 2011-2015; (**Exhibit 30**)
60. Knospe et al. (1966) Blood 28, pages 398-415; (**Exhibit 31**)
61. Knospe et al. (1972) Blood 39, pages 331-340; (**Exhibit 32**)
62. Lichtman (1981) Experimental Hematology 9, page 391-410; (**Exhibit 33**)
63. Long (1992) Experimental Hematology 20, pages 288-301; (**Exhibit 34**)
64. McManus and Weiss (1984) Blood 64, pages 1036-1041; (**Exhibit 35**)
65. McIntyre and Bjornson (1986) Exp. Hematol. 14, pages 833-839; (**Exhibit 36**)
66. Miltenyi et al. (1990) Cytometry 11, pages 231-238; (**Exhibit 37**)
67. Owen (1985) Bone and Mineral Research 3, pages 1-25; (**Exhibit 38**)
68. Owen and Friedenstein (1988) CIBA Found. Symposium 136, pages 42-60; (**Exhibit 39**)

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Page 7

69. Perkins and Fleischman (1990) Blood 75, pages 620-625;
(Exhibit 40)
70. Piersma et al. (1983) Br. J. Haematol. 54, pages 285-290;
(Exhibit 41)
71. Rothstein et al. (1985) Blood 65, page 744; (Exhibit 42)
72. Simmons and Gronthos (1991) Int'l J. of Cell Cloning 9,
page 408 (abstract); (Exhibit 43)
73. Simmons, P.J., et al. (1994) "Isolation, Characterization
and Functional Activity of Human Marrow Stromal Progenitors
in Hemopoiesis" Advances in Bone Marrow Purging and
Processing: Progress in Clinical and Biological Research;
Fourth Int'l Symposium 389, pages 271-280; (Exhibit 44)
74. Simmons et al. (1987) Nature 328, pages 429-432; (Exhibit
45)
75. Simmons and Torok-Storb (1991) Blood 78, pages 55-62;
(Exhibit 46)
76. Simmons and Torok-Storb (1991) Blood 78, pages 2848-2853;
(Exhibit 47)
77. Tavassoli and Friedenstein (1983) Ann. J. Hematol. 15,
pages 195-203; (Exhibit 48)
78. Tavassoli and Crosby (1968) Science 161, pages 54-56;
(Exhibit 49)
79. Testa et al. (1988) "Long-Term Bone Marrow Damage After
Cytotoxic Treatment: Stem Cells and Microenvironment in
Hematopoiesis: Long-Term Effects of Chemotherapy and
Radiation" Hematol. Published by Marcel & Deaker, Inc. 8,
pages 75-91; (Exhibit 50)
80. Van Vlasselaer et al. (1994) Blood 84, pages 753-763;
(Exhibit 51)

81. Waller et al. (1995) Blood 85, pages 2422-2435; (**Exhibit 52**)
82. Weiss (1976) Anatomical Record 186, pages 161-184; (**Exhibit 53**)
83. Zóltowska A, Stepiński J, Lewko B, Zamorska B, Roszkiewicz A, Serkies K, and Kruszewski WJ. (2001) Malformations of Angiogenesis in the Low Differentiated Human Carcinomas. Immunohistochemical Study. Arch. Immunol. Ther. Ex. 49: 59-61; (**Exhibit 54**)
84. Axelrad et al., New Technologies for the Enhancement of Skeletal Repair, Injury, Int. J. Care Injured (2007) 38S1:S49-S62; (**Exhibit 55**)
85. Bruder et al., Mesenchymal Stem Cells in Bone Development, Bone Repair, and Skeletal Regeneration Therapy, J. Cell Biochem; (1994) 56:283-294; (**Exhibit 56**)
86. Dennis et al., Osteogenesis in Marrow-Derived Mesenchymal Cell Porous Ceramic Composites Transplanted Subcutaneously: Effect of Fibronectin and Laminin on Cell Retention and Rate of Osteogenic Expression, Cell Transplant (1992) 1:23-32, Abstract; (**Exhibit 57**)
87. Zvaifler, et al., (2000) "Mesenchymal precursor cells in the blood of normal individuals," Arthritis Research and Therapy, 2: 477-488; (**Exhibit 58**)
88. Ji, et al., (2004) "Interactions of Chemokines and Chemokine Receptors Mediate the Migration of Mesenchymal Stem Cells to the Impaired Site in the Brain After Hypoglossal Nerve Injury," Stem Cells, 22: 415-427; (**Exhibit 59**)
89. Sordi, et al., (2005) "Bone marrow mesenchymal stem cells express a restricted set of functionally active chemokine

- receptors capable of promoting migration to pancreatic islets," Blood, 106(2): 419-427; (**Exhibit 60**)
90. Wynn, et al., (2004) "A small proportion of mesenchymal stem cells strongly expresses functionally active CXCR4 receptor capable of promoting migration to bone marrow," Blood, 104(9): 2643-2645; (**Exhibit 61**)
91. Kortessidis, et al., (2005) "Stromal-derived factor-1 promotes the growth, survival, and development of human bone marrow stromal stem cells," Blood, 105(10): 3793-3801; (**Exhibit 62**)
92. Gronthos, S., et al., (1999) "Differential Cell Surface Expression Of The STRO-1 And Alkaline Phosphatase Antigens On Discrete Developmental Stages In Primary Culture Of Human Bone Cells," Journal of Bone and Mineral Research, 14(1): 47-56; (**Exhibit 63**)
93. Stewart, K., et al., (1999) "Further Characterization Of Cells Expressing STRO-1 In Cultures Of Adult Human Bone Marrow Stromal Cells," Journal of Bone and Mineral Research, 14(8): 1345-1356; (**Exhibit 64**)
94. International Search Report issued by the International Searching Authority (ISA/AU) on August 22, 2005 in connection with International Application No. PCT/AU2005/000953; (**Exhibit 65**)
95. International Search Report issued by the International Searching Authority (ISA/AU) on November 25, 2005 in connection with International Application No. PCT/AU2005/001445; (**Exhibit 66**)
96. Office Action issued January 12, 2005 in connection with U.S. Serial No. 10/030,411; (**Exhibit 67**)

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97. Office Action issued June 28, 2005 in connection with U.S. Serial No. 10/030,411; (**Exhibit 68**)
98. Final Office Action issued January 9, 2006 in connection with U.S. Serial No. 10/030,411; (**Exhibit 69**)
99. Office Action issued April 20, 2007 in connection with U.S. Serial No. 10/955,709; (**Exhibit 70**)
100. Office Action issued August 24, 2007 in connection with 11/178,920; (**Exhibit 71**)
101. Office Action issued August 25, 2006 in connection with U.S. Serial No. 10/955,709; (**Exhibit 72**)
102. Examiner Interview Summary issued June 27, 2006 in connection with U.S. Serial No. 10/030,411; (**Exhibit 73**)
103. Office Action issued August 24, 2007 in connection with U.S. Serial No. 11/178,920; (**Exhibit 74**)
104. Office Action issued December 15, 2006 in connection with U.S. Serial No. 11/178,920; (**Exhibit 75**)
105. Office Action issued July 10, 2006 in connection with U.S. Serial No. 11/178,920; (**Exhibit 76**)
106. Office Action issued January 22, 2007 in connection with U.S. Serial No. 11/169,875; (**Exhibit 77**)
107. Office Action issued July 10, 2006 in connection with U.S. Serial No. 10/813,747; (**Exhibit 78**)
108. Office Action issued December 15, 2006 in connection with U.S. Serial No. 10/813,747; (**Exhibit 79**)
109. Office Action issued April 3, 2007 in connection with U.S. Serial No. 10/813,747; (**Exhibit 80**)
110. Office Action issued October 19, 2007 in connection with U.S. Serial No. 10/813,747; (**Exhibit 81**)
111. Restriction Requirement issued January 8, 2008 in connection with U.S. Serial No. 11/326,736; (**Exhibit 82**)

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112. Final Office Action issued January 10, 2008 in connection with U.S. Serial No. 10/955,709; (**Exhibit 83**)
113. Extended European Search Report issued December 27, 2007 in connection with European Application No. 05787106.3; (**Exhibit 84**)
114. Supplementary European Search Report issued January 2, 2008 in connection with European Application No. 05754008.0; (**Exhibit 85**)
115. Cochlovius, B. et al. (2003) "Therapeutic Antibodies," Modern Drug Discovery pp 33-34, 37-38; (**Exhibit 86**)
116. Gronthos et al. Journal of Hematotherapy, 1996. 5, 15-23 (Abstract); (**Exhibit 87**)
117. Hansson, M. et al. (2007) "Commentary: Isolated Stem Cells - Patentable as Cultural Artifacts?" V.25, pp. 1507-1510; (**Exhibit 88**)
118. Pan, Beiying et al. (2004) "The nitrogen-containing bisphosphonate, zaledronic acid, increases mineralisation of human bone-derived cells in vitro." Bone 34:112-123; (**Exhibit 89**)
119. Cassiede, P. et al. (1996) "Osteochondrogenic Potential of Marrow Mesenchymal Progenitor Cells Exposed to TGF- β 1 or PDGF-BB as Assayed In Vivo and In Vitro" *Journal of Bone and Mineral Research* Vol. 11(9):1264-1273; (**Exhibit 90**)
120. Kang Yong Jung et al. (2004) "Involvement of PI-3-kinase, JNK, PKC, and PKA in the PDGF-induced proliferation in human adipose tissue-derived mesenchymal stem cells" Vol. 18(8) Pg. C253; (**Exhibit 91**)
121. U.S. Serial No. 11/663,570, filed March 23, 2007; and (**Exhibit 92**)

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122. U.S. Serial No. 11/663,563, filed March 23, 2007. (**Exhibit 93**)

Item 118 was cited in an Extended European Search Report issued December 27, 2007 in connection with European Application No. 05787106.3, a copy of which is attached hereto as **Exhibit 84**.

Items 21, 119 and 120 were cited in a Supplementary European Search Report issued January 2, 2008 in connection with European Application No. 05754008.0, a copy of which is attached hereto as **Exhibit 85**.

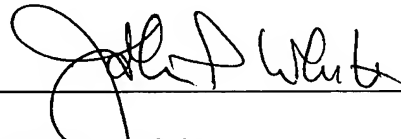
This Supplemental Information Disclosure Statement is being submitted under 37 C.F.R. §1.97(b)(3) before the issuance of a first Office Action on the merits. The Examiner is respectfully requested to make these items of record in the present application by initialing and returning a copy of the enclosed Substitute Form PTO-1449.

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If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

Pursuant to 37 C.F.R. §1.97(b)(3), no fee is deemed necessary in connection with the filing of this Supplemental Information Disclosure Statement. However, if any fee is required authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

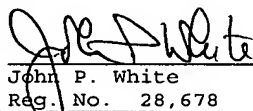
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